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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,370	12/21/2001	Jeffrey A. Trogolo	A-036	5277

7590

06/12/2003

AGION TECHNOLOGIES
60 Audubon Road
Wakefield, MA 01880

EXAMINER

BENNETT, RACHEL M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,370

Applicant(s)

TROGOLO ET AL.

Examiner

Rachel M. Bennett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 33, 34 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 33, 34 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z. 6) ☐ Other:

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DETAILED ACTION

The examiner acknowledges receipt of Amendment A and IDS filed 3/31/03.

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-22, 33-34 in Paper No. 6 is acknowledged.

Specification

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 4, 5, 18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants do not clearly define in the instant claims or the specification "ion exchange type agents". The addition of the word "type" to an otherwise definite expression extends the scope of the expression so as to render it indefinite. Likewise, the phrase "ion exchange type agents" is indefinite because it is unclear what "type" is intended to convey. Clarification is requested.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-18, 22, 33, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. (US 6436422).

Applicants claim a high aspect ratio microcapsule comprising an antimicrobial agent coated with a hydrophilic polymer, said microcapsule having an aspect ratio of greater than about 2. Applicants define aspect ratio as the ratio of the longest dimension of a three-dimensioned particle to the shortest dimension. Generally, the high aspect ration antimicrobial microcapsules include microcapsules that are in the shape of flakes or sheets as well as those that are in the shape of fibers or cylinders. Other shapes, such as football and other oblong shapes are suitable as well. See instant specification page 5.

Trogolo discloses an antibiotic coated substrate having an antibiotic coating composition coated thereon. The coating composition is formed of a hydrophilic polymer having antibiotic ceramic particles, preferably antibiotic zeolite dispersed therein. The antibiotic zeolite may further comprise a discoloration agent. See abstract. Antibiotic ceramic particles include zeolites, hydroxyapatite, zirconium phosphates and other ion-exchange ceramics. Any suitable hydrophilic polymer may be employed, including hydrophilic polyurethane. In antibiotic zeolite particles used in the preferred embodiment, ion-exchangeable ions present in zeolite, such as

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sodium ions, calcium ions, potassium ions and iron ions are partially replaced with ammonium and antibiotic metal ions. Such ions may co-exist in the antibiotic zeolite particle since they do not prevent the bactericidal effect. Examples of antibiotic metal ions include, ions of silver, copper, zinc, mercury, tin, lead, bismuth, cadmium, chromium and thallium. Preferably, the antibiotic metal ions are silver, copper, or zinc ions, and most preferably silver is employed. These antibiotic metal ions may be incorporated into the zeolite by themselves or in a mixture. See col. 3 lines 21-65. A discoloration agent may be added to the antibiotic hydrophilic polymer. The inorganic discoloration inhibitor is an ion-exchanged ammonium ion in the antibiotic zeolite. The substrate may be any substrate to which the hydrophilic polymer adheres, including glass, plastic, metal, and woven and non-woven fabrics. An article comprising a substrate on which is coated with the antibiotic hydrophilic coating may also be used. The article may be a medical article, such as a catheter, stent, heart valve, or paper. See col. 5 lines 22-55. The solids in the coating solution preferably contain from about 0.01 to about 90% by weight of antibiotic zeolite and from about 10% to about 99.99% by weight of hydrophilic polymer. Trogolo is silent with regards to the aspect ratio, specifically an aspect ratio greater than about 2.

While the reference is silent regarding the aspect ratio, difference in the aspect ratio will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such an aspect ratio is critical. Where the general conditions of the claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Trogolo discloses the similar microcapsules as desired by Applicants. Trogolo discloses sheets, fibers and cylinders. See Figure 1 and col. 5. Therefore, absent

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unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the microcapsule do determine a suitable aspect ratio to achieve the desired results.

7. Claims 1-22, 33-34, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. (US 6436422) and further in view of Michal et al. (US 6287285).

Applicants claim a high aspect ratio microcapsule comprising an antimicrobial agent coated with a hydrophilic polymer, said microcapsule having an aspect ratio of greater than about 2. Applicants define aspect ratio as the ratio of the longest dimension of a three-dimensioned particle to the shortest dimension. Generally, the high aspect ration antimicrobial microcapsules include microcapsules that are in the shape of flakes or sheets as well as those that are in the shape of fibers or cylinders. Other shapes, such as football and other oblong shapes are suitable as well. See instant specification page 5.

Trogolo, as disclosed above, teaches an antibiotic coated substrate having an antibiotic coating composition coated thereon. Trogolo does not disclose the microcapsule comprise a dopant, specifically sodium nitrate.

Michal discloses a method of providing a therapeutic, diagnostic or lubricious hydrophilic coating on and intracoporeal medical device. See abstract. Additionally, nitric oxide donor drugs may be used as a vasodilator relaxing smooth muscles of a vessel prior to, during, and/or after angioplasty or stent placement. A variety of suitable nitric-oxide donor drugs include sodium nitrate. See col. 4.

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the

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composition of Trogolo by adding a dopant, specifically sodium nitrate as taught by Michal because of the expectation of relaxing smooth muscles of a vessel prior to, during, and/or after angioplasty or stent placement. Both Trogolo and Michal teach medical devices, specifically spents coated with a hydrophilic polymer. Therefore, it would have been obvious to add sodium nitrate to the composition of Trogolo for the added benefits taught by Michal. The expected result would be a microcapsule comprising a hydrophilic polymer, an antimicrobial agent and a dopant.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett
June 5, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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